UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

24

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,250	08/21/2001	Wenbin Dang	GPT-029.01	6514

29755 7590 04/12/2005

FOLEY HOAG LLP
PATENT GROUP, WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02110-2600

EXAMINER	
HUI, SAN MING R	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 04/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/934,250	DANG ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,22-26 and 30-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,22-26 and 30-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments filed December 10, 2004 have been entered. The cancellation of claims 19-21 and 27-29 is acknowledged.

Claims 1-18, 22-26, and 30-41 are pending.

The outstanding rejections under 35 USC 112 have been withdrawn in view of the amendments and remarks filed December 10, 2004.

The outstanding rejections under 35 USC 102 are withdrawn in view of the amendments filed December 10, 2004.

The outstanding rejection under 35 USC 103 is withdrawn in view of the amendments filed December 10, 2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14, 17, 22-24, 26, 32-33, and 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by US 2,676,961 ('961) as evidence provided by Merck Index (1989, 11th ed., monograph 7042).

'961 teaches a suspension intramuscular composition comprising about 30% (300,000units in 1ml) of procaine-penicillin by weight in peanut or sesame oil (see col. 4-5, Examples 3-4).

Merck Index teaches that the potency of Penicillin of procaine penicillin as 1000units/mg.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15-16, 18, 25, and 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over '961.

'961 teaches a suspension composition comprising about 30% (300,000units in 1ml) of procaine-penicillin by weight in peanut or sesame oil (see col. 4-5, Examples 3-4).

'961 does not expressly teach the herein claimed weight amount of the caine analgesic or the biocompatible oil. '961 does not expressly teach the instruction of administration of the intramuscular composition.

It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the herein claimed weight amount of the caine analgesic or the biocompatible oil into the intramuscular composition of '961. It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate administration instruction with the intramuscular composition.

One of ordinary skill in the art would have been motivated to incorporate the herein claimed weight amount of the caine analgesic or the biocompatible oil into the intramuscular composition of '961 since the adjusting the antibiotic agent to treat various bacterial infection would be a routine practice to a clinician. As anyone of ordinary skill in the art will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. There are, however, many reasons for varying dosages, including by orders of magnitude; for instance, an extremely heavy patient or one having an unusually severe infection would require a correspondingly higher dosage. Furthermore, it is routine during animal and clinical studies to dramatically vary dosage to obtain data on parameters such as toxicity.

One of ordinary skill in the art would have been motivated to incorporate administration instruction with the intramuscular composition. The inclusion of a package insert or label showing the "the name of drug, dosage, dosage form, route of administration, indication and **direction of use**" [emphasis added] of a pharmaceutical

composition is mandated by 21 CFR 201.57 and is therefore obvious to one of ordinary skill in the art.

Claims 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 3,105,793 (herein after as '793).

'793 teaches a parenteral composition containing lidocaine hydrochloride (See claim 5).

'793 does not expressly teach the herein claimed amount of lidocaine hydrochloride.

It would have been obvious to one of ordinary skill in the art at the time of invention to adjust to the amount of lidocaine hydrochloride of composition of '793 to more than 3%.

One of ordinary skill in the art would have been motivated to adjust to the amount of lidocaine hydrochloride of composition of '793 to more than 3%. Absent evidence to the contrary, as discussed above, the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Primary Examiner
Art Unit 1617